

# Claims

- [c1] A data collection and monitoring system, comprising:
- a. a remote collection unit means for collecting medical data, validating said collected data, and storing data therein;
  - b. instruction means within the remote collection unit for guiding the user of the data collection and monitoring system through various procedural steps for the collection of data;
  - c. display means on the remote collection unit for displaying data, instruction windows and graphics pertaining to each protocol study to the user of the remote collection unit;
  - d. input means connected to the remote collection unit to allow the user of the remote collection unit the ability to interact with the data displayed in real time, wherein the user may edit the information shown on the display or input new information into the remote collection unit;
  - e. interface means connected to the remote collection unit for downloading new or updated protocol details from the design repository and uploading data from the remote collection unit to the data repository; and
  - f. a main computer system connected to the interface

means for receiving the uploaded data for further processing and downloading new or modified collection instructions to the remote collection unit.

[c2] [Claim Reference]The method according to Claim 1, wherein a method for defining parameters for data collection on the remote collection unit is defined, comprising the steps of:

- a. creating, changing, or deleting protocol details, component parameters, and data values and storing those details, parameters, and values in a design repository;
- b. generating a set of source code using the values stored in the design repository as input;
- c. further generating a target application from the source code generated from the values stored in the design repository;
- d. transforming the target application into a form that can be deployed on the remote collection unit; and
- e. transmitting the transformed target application to the remote collection unit.

[c3] [Claim Reference]A method for consolidating data collected by the remote collection unit as recited in claim 2, comprising the steps of invoking a data import and export module to upload the collected data from the remote collection unit to one or more of a plurality of centralized data repositories.

- [c4] [Claim Reference] A method for consolidating data collected by the remote collection unit as recited in claim 2, comprising the steps of:
- a) invoking a data import and export module to upload the collected data in a hierarchical configuration from the remote collection unit to one or more of a plurality of site-managed data repositories; and
  - b) transmitting data from all site-managed data repositories to a centralized data repository.